

## **Remarks**

Claims 1-23 are currently pending in the Subject Application. Claims 21-23 are new. A Petition for a three-month extension of time is enclosed herewith.

## **Claim Rejections**

### **35 U.S.C. §103(a) Cummings '951 in view of Hatanaka '908**

Independent Claim 9, and Dependent Claims 10-12, 14-16, and 19-20, have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,744,951 to Cummings et al. ("Cummings '951") in view of European Patent Application No. 0 321 908 to Hatanaka et al. ("Hatanaka '908").

Independent Claim 9, as amended, recites a method of providing a vapor phase sterilant to a sterilization chamber comprising the steps of creating temperature and pressure conditions within a vaporizer sufficient to vaporize the sterilant, **using a vacuum inducing device to lower the pressure within the vaporizer to a pressure below atmospheric pressure**, admitting the sterilant, in its liquid phase, into the vaporizer and vaporizing the sterilant, passing the sterilant through a circuitous path, **collecting non-vaporizable components of the sterilant** on surfaces forming the circuitous path, then passing the sterilant, in its vapor phase, through a flow restriction, and passing the sterilant, in its vapor phase, out of the vaporizer.

The combination of Cummings '951 in view of Hatanaka '908 is improper for at least three reasons. **First**, the combination does not disclose or suggest all of the above-recited claim recitations of amended Independent Claim 9. *In re Wilson* states that, in reference to rejections under 35 U.S.C. §103(a), "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.", 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A.

1970), see also, MPEP §2143.03. Neither Cummings '951 nor Hatanaka '908 discloses or suggests the collection of non-vaporizable components of a sterilant, let alone in a sub-atmospheric environment.

**Second**, the teachings of Cummings '951 in view of the teachings of Hatanaka '908 are in direct contradiction to one another, let alone the claimed vaporization method of Independent Claim 9. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). In short, Cummings '951 teaches a vaporization system which draws water vapor out of a vaporized hydrogen peroxide solution to **increase the concentration** of the vaporized hydrogen peroxide solution prior to flowing the vaporized solution into a sterilization chamber (see Cummings '951, Abstract). On the contrary, Hatanaka '908 discloses admitting a hot carrier gas into a vaporizer such that the hot carrier gas can be mixed with a vaporized hydrogen peroxide solution (see Hatanaka '908, col. 3, lines 4-14). Applicants submit that the admission of the hot carrier gas into the vaporizer of Hatanaka '908 **deceases the concentration** of the vaporized hydrogen peroxide solution before the vaporized solution is introduced into a sterilization chamber, which is in direct contradiction with the teachings of Cummings '951. Further, Applicants submit that the influx of the hot carrier gas of Hatanaka '908 into the vaporizer will, if anything, increase the pressure within the vaporizer instead of operating the vaporizer at a pressure below atmospheric pressure and, as a result, it is clear that Hatanaka '908 teaches away from the claimed invention.

**Third**, the combination of Cummings '951 in view of Hatanaka '908 changes the principle of operation of the Cummings '951 device. The MPEP instructs that "[I]f the proposed

modification or combination of the prior art would **change the principle of operation of the prior art invention** being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. MPEP § 2143.01, see also, *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (emphasis added). Applicants submit that the combination of Cummings '951 in view of Hatanaka '908 changes the principle of operation of Cummings '951, the primary reference. The principle of operation of Cummings '951 is to **increase the concentration of hydrogen peroxide** within a hydrogen peroxide solution by drawing water vapor out of the hydrogen peroxide solution. As a result, this primary principle of operation of Cummings '951 is defeated when combined with Hatanaka '908's vaporizer, as Hatanaka '908 teaches to **decrease the concentration of hydrogen peroxide** within a hydrogen peroxide solution owing to the influx of the hot carrier gas.

For at least the reasons advanced above, Independent Claim 9, and the claims depending therefrom, should be allowed.

35 U.S.C. §103(a) Hatanaka '908 in view of Hatanaka '255

Independent Claims 13 and 17, and Dependent Claim 18, have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hatanaka '908 in view of U.S. Patent No. 4,797,255 to Hatanaka et al. ("Hatanaka '255").

Independent Claims 13 and 17, as amended, both recite, among other things, a method of providing a vapor phase sterilant to a sterilization chamber comprising the steps of **using a vacuum inducing device** to lower the pressure within a vaporizer to a **pressure below atmospheric pressure** and **collecting non-vaporizable components of a sterilant** on surfaces forming a circuitous path. Independent Claim 17, also recites wherein at least 75% of the non-

vaporizable components are removed from the sterilant prior to the step of passing the sterilant out of the vaporizer.

The combination of Hatanaka '908 in view of Hatanaka '255 does not disclose or suggest, among other things, the above-recited recitations of amended Independent Claims 13 and 17, as required under 35 U.S.C. §103, by *In re Wilson, supra*. Neither Hatanaka '908 nor Hatanaka '255, either alone or in combination, discloses or suggests sterilization at a **pressure below atmospheric pressure**.

By not performing its vaporization at a pressure below atmospheric pressure, Hatanaka '908 and Hatanaka '255 cannot achieve at least three benefits of the claimed invention. **First**, vaporization at a sub-atmospheric pressures can provide a margin of safety should a leak develop anywhere in the vaporizer. In the event that the claimed vaporizer were to develop a leak, air would rush into the system at the leak, as opposed to sterilant vapor rushing out as would likely occur in the vaporizers disclosed in Hatanaka '908 and Hatanaka '255. Sterilant vapors leaking out of a vaporizer may have various undesirable consequences. **Second**, it is often important to at least partially remove the air, or other gases, from within the vaporizer prior to or during the vaporization process because these gases may lead to ineffective sterilization and/or contamination within the vaporizer. The claimed vaporizer not only removes these gases, but also removes at least a portion of the non-vaporizable components of the sterilant to reduce the possibility that these non-vaporizable components will be deposited on various devices being sterilized. **Third**, the sub-atmospheric conditions provided by the claimed vaporizer can aid in the diffusion of sterilant vapor into long, narrow lumens of various devices being sterilized leading to a more efficient sterilization process. Under super-atmospheric conditions, as taught in Hatanaka '908 and Hatanaka '255, the sterilant vapor is, to some extent, inhibited from

entering and sterilizing these long, narrow lumens, owing to the positive pressure within the lumens. For the reasons advanced above, Independent Claims 13 and 17, and the claims depending therefrom, should be allowed.

35 U.S.C. §102(b)/35 U.S.C. §103(a) in view of Hatanaka '908

Independent Claim 1, and Dependent Claims 2, 3, and 6, have been rejected under 35 U.S.C. §102(b) as being anticipated by European Patent Application No. 0 321 908 to Hatanaka et al. ("Hatanaka '908"). Independent Claim 5, and Dependent Claims 4 and 7-8, have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hatanaka '908.

Independent Claim 1, as amended, recites, among other things, a vaporizer for vaporizing a sterilant from its liquid phase in a vapor phase sterilization system having a **pressure below atmospheric pressure**, the vaporizer comprising a **removable core including a circuitous path**, wherein the removable core is positioned at least partially between an inlet and an outlet, and wherein the **circuitous path is configured to collect a first portion of non-vaporizable ingredients of the sterilant**, a flow restriction between the circuitous path and the outlet, wherein the flow restriction is configured to cause a **second portion of the non-vaporizable ingredients to collect on a surface of the vaporizer** prior to the vapor phase sterilant being admitted to a sterilization chamber, and a **vacuum pump** in fluid communication with the vaporizer, **wherein the vacuum pump is configured to create a vacuum within the circuitous path**. Independent Claim 5, as amended, includes similar recitations as Independent Claim 1 and also includes the recitation of a flow restriction comprising an orifice defined in an orifice plate positioned one of over an opening of the outlet tube and within the outlet tube,

wherein the orifice includes a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice.

In addition to the deficiencies discussed above, Hatanaka '908 does not disclose or suggest a **removable core including a circuitous path configured to collect a first portion of non-vaporizable ingredients of a sterilant, a vacuum pump configured to create a vacuum within the circuitous path, or a flow restriction configured to cause a second portion of the non-vaporizable ingredients to collect on a surface of the vaporizer.** In fact, as discussed above, Hatanaka '908 does not disclose or suggest collecting non-vaporizable ingredients **at all**, let alone in a **sub-atmospheric environment**.

In various exemplary embodiments, the Subject Application discloses a removable core 66 that fits within a housing 44. In at least one embodiment, the removable core 66 includes the circuitous path. In various embodiments, the removable core 66 can be positioned within the housing 44 and removed from the housing 44 such that the non-vaporizable components of a sterilant collected on the removable core 66 can be rinsed or removed from the circuitous path during a cleaning process. See e.g., para. [0030].

Further, Hatanaka '908 does not render Independent Claims 1 and 5 obvious as there is no apparent reason why a person of ordinary skill in the art would use the vaporizer of Hatanaka '908 in sub-atmospheric conditions to remove non-vaporizable ingredients of a sterilant. In fact, Hatanaka '908 does not disclose or suggest that it **even could be used** to remove non-vaporizable components of a sterilant. As the Examiner is aware, he bears the burden of providing an **apparent reason** for combining the teachings of the cited references and such an apparent reason must be express. *KSR International Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727 (2007). In view of the above, Applicants respectfully submit that the Examiner has not provided

a legally sufficient apparent reason. As a result, the Applicants submit that the 35 U.S.C. §103(a) rejections of Independent Claim 5, and the claims depending therefrom, are based solely on impermissible hindsight. As stated in §2142 of the MPEP:

The tendency to resort to “hindsight” based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight **must be avoided** and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

MPEP §2142 (emphasis added), *see also, In re Deminski*, 796 F.2d 436, 443 (Fed. Cir. 1986).

For at least the reasons advanced above, the Applicants respectfully request withdrawal of the 35 U.S.C. §102(b) and 35 U.S.C. §103(a) rejections of Independent Claims 1 and 5, respectively, and the claims depending therefrom, in view of Hatanaka ‘908, and request allowance thereof at an early date.

#### 35. U.S.C. §112, first paragraph

Independent Claim 9 has been rejected under 35 U.S.C. §112, first paragraph. More specifically, the Examiner has asserted that the recitation “admitting no carrier gas into the vaporizer” has no literal basis in the disclosure. While the Applicants respectfully disagree with the Examiner, Applicants submit that this rejection has been rendered moot in view of the amendment made to Independent Claim 9 in the present Amendment.

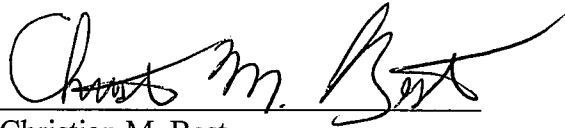
#### New Independent Claim 21

None of the references cited in the Office Action disclose or suggest all of the recitations of new Independent Claim 21 and, therefore, the Applicants respectfully request allowance of new Independent Claim 21, and the claims depending therefrom.

## Conclusion

Applicants respectfully submit that all of the claims presented in the Subject Application are in condition for allowance. Applicants' present Amendment should not in any way be taken as acquiescence to any of the specific assertions, statements, etc., presented in the Office Action not explicitly addressed herein. Applicants reserve the right to specifically address all such assertions and statements in subsequent responses. If the Examiner has any remaining concerns, the Examiner is invited to contact the undersigned at the telephone number set forth below so that such concerns may be expeditiously addressed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Christian M. Best", written over a horizontal line.

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